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EXAMINER	
MARVICH, MARIA	
ART UNIT	PAPER NUMBER
1633	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/19/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/072,766	SLEPIAN, MARVIN J.	
	Examiner	Art Unit	
	Maria B. Marvich, PhD	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4 and 6-37* is/are pending in the application.

4a) Of the above claim(s) *8-12,26,27 and 30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4, 6,7,13-25,28,29 and 31-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 July 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/7/06 and 9/25/06 has been entered.

Upon reconsideration, the restriction requirement between Groups I and II has been withdrawn. Thus, claims 4 and 32 have been rejoined with the instantly examined claims. Therefore, claims 1, 3, 4, 6, 7, 13-25, 28, 29 and 31-37 are under examination in this office action.

Claim Objections

Claim 1 is objected to because of the following informalities: "polymeric carrier" is written in singular but should be drafter in the plural for consistency with the remainder of the claim.

Claim 1 has been amended to recite that the method of treatment comprises "penetrating into" which is grammatically incorrect as the claims do not recite what is penetrated. For clarity it would be remedial to recite -- penetrating into the endomural zone --.

Claim 35 is objected to because of the following informalities: in the amendment to claim 35, applicants have added the term "penetrated" to replace the term "accessed" but have not deleted the term "accessed".

Appropriate correction is required.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 6-7 and 13-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This rejection is maintained for reasons of record in the office action mailed 9/7/05 and restated below.**

The limitation that the agents are delivered in "a carrier selected from the group consisting of polymeric carrier, porous matrices, hydrogels, organogels, colloidal suspensions, microparticles and microcapsules, nanoparticles and combinations thereof" has been added to claims 1 and 15. Applicants have not indicated where support for this limitation is found. Original claim 5 recites that the therapeutic agent can be a polymer that is a solid matrix, porous matrix, hydrogel etc. Neither this recitation nor the remainder of the specification teach use of any carrier that is any porous matrix, hydrogel, colloidal suspension, microparticle, microcapsule, nanoparticle or combination. As well, the specification teaches that therapeutic agents can be delivered to the endomural zone using polymers. However, the combination of these teachings does not teach that these structures are intended as carriers. Furthermore, these claims do not limit the carriers to polymers. Original claim 5 is limited to use of polymers as

therapeutic agents that comprise porous matrix, hydrogel, colloidal suspension, microparticle, microcapsule, nanoparticle or combination. Therefore the limitation is impermissible NEW MATTER.

Response to Argument

Applicants traverse the claim rejections under 35 U.S.C. 112, first paragraph on page 8 of the amendment filed 9/25/06. Applicants argue that support for use of a polymer as a carrier is described throughout the specification.

Applicants' arguments filed 9/25/06 have been fully considered but they are not persuasive. The limitation that the agents are delivered in "a carrier selected from the group consisting of polymeric carrier, porous matrices, hydrogels, organogels, colloidal suspensions, microparticles and microcapsules, nanoparticles and combinations thereof" is not found in the specification. The specification discloses that polymers can be used to deliver bioactive agents to the endomural zone, however, the claims are not limited to use of polymers to deliver the agents. Rather the claims recite a rather broad genus of carriers that are not disclosed in the specification and as such the limitation is impermissible new matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 14, 18, 19 and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

applicant regards as the invention. **This rejection is maintained for reasons of record in the office action mailed 9/7/06 and restated here.**

Claim 14 is vague and indefinite in that the metes and bounds of "first" are unclear. It is unclear to what the "first" refers. The dependent claim is included in the rejection because they fail address or clarify the basis of the rejection as discussed in detail for the independent claim. Because the term "first" is relative it is unclear to what it refers, and suggests that this step happens prior to any of the method steps of claim 1. This is confusing as claim 14 recites that the organ is penetrated and cut or tissue is removed. Therefore, it is unclear if the cavity, containment space or reservoir is the void created in claim 1 or if the step of claim 14 is intended to be a distinct step generating a distinct space. **This is a new rejection necessitated by applicants' amendment.**

Claim 18 is vague and indefinite in that the metes and bounds of use of the reservoir(s) for delivery are unclear. The device of claim 15 recites that the device comprises a means for local delivery. It is unclear if the reservoir is intended to be this means for delivery and if so, how it functions to deliver the agents to the endomural zone. **This is a new rejection.**

Claim 19 is vague and indefinite in that the metes and bounds of "expansile cutter at an end of the member to create a void" are unclear. It is unclear if this expansile cutter is in addition to the end means of claim 15 that is used to create a void or the same structure. **This is a new rejection.**

Response to Argument

Applicants traverse the claim rejections under 35 U.S.C. 112, second paragraph on page 8-9 of the amendment filed 9/25/06. Applicants argue that the claims have been amended to indicate that a void is created in the tissue and that a space is created into which material is deposited.

Applicants' arguments filed 9/25/06 have been fully considered but they are not persuasive. Claim 14 is unclear as it is unclear when the step of first forming a cavity, containment space or reservoir occurs and given that a void is created in claim 1 already, it is not clear if this void is the cavity, containment area or reservoir.

Claim interpretation

The instant specification has described the endomural zone as the middle zone of an organ, organ component or tissue structure. As guidance, applicants have described the endomural zone to correspond roughly to the central 80% of these structures. In the heart, the myocardium fits this description as evidence in the accompanying drawings in Ross (Composition of the Heart, online article June 1999). Specifically, as evidenced in the drawings depicting the layers of the heart, the endocardium and epicardium surround the myocardium. The myocardium is roughly 80% of the heart layer. In the spinal cord, the lateral corticospinal tract appears to be in the area of the spinal cord that can be considered the endomural zone as evidenced by William et al (The Human Brain: Dissection of the Real Brain, January 1997, Chapter 1). Roughly 80% of the spinal cord is comprised of central cord, which encompasses the lateral corticospinal region.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 4, 6, 7, 15-18, 20-23, 25, 28, 29, 32 and 35-37 are rejected under 35 U.S.C. 102(e) as being anticipated by Altman (US 6,585,716 B2; see entire document). **This rejection is maintained from the office action mailed 10/4/04 and 9/7/05 and restated below.**

Altman teaches a drug delivery device for methods of treating the heart for injecting therapeutic agents into the myocardium. The method involves penetrating and entering the endomural zone (myocardium) with delivery of the agents to the endomural zone. Agents are delivered in microformulations such as microspheres (encompassing microcapsules and microparticles). The agents are delivered using a tubular "means for delivery", which is a means of delivery similar to that disclosed in the instant specification. The combination of the microspheres and drug delivery catheter would be said to place the agents in "a form for local delivery" as recited in claim 1. As well., Altman et al teach that controlled release matrices such as those made of polymers can be used to deliver the drug (see e.g. col 6, line 8-13) as recited in claims 3 and 4 and together create a bioactive polymer as recited in claim 32. Drugs used include growth factors and peptides and angiogenesis agents (see e.g. col 5, line 48-56 and col 4, line 1) or drugs as recited in claim 3, 6, 7, 28 and 29. The delivery device has a guidance system

as recited in claim 23 and a hollow penetrating element i.e. a needle attached to a catheter as recited in claim 36 and 37 (see e.g. bridging paragraph col 3-4). The instant specification teaches that the means for creating a void can be a simple catheter or needle. Therefore, the needle of Altman et al creates a void by insertion and exit from the tissue similar to that recited in claim 15 and 25 and is comprised of metal as recited in claim 16. The catheter is flexible as recited in claim 17. Drugs are stored in a reservoir attached to the catheter and pumped automatically into the lumen of the drug delivery catheter through the penetrating element into the target (see e.g. col 5, line 15-39) as recited in claim 18, 21 and 22. Furthermore, sensors can be used with the device for electrical sensing (see e.g. col 5, line 65-67) as recited in claim 20. The delivery can be percutaneously or surgically (see e.g. col 5 , line 23-28) as recited in claim 35.

Claims 1, 3, 6, 7, 15-18, 19, 21-23, 25, 34, 36 and 37 are rejected under 35 U.S.C. 102(e) as being anticipated by Altman (US 6,102,887; see entire document). **This rejection is maintained from the office action mailed 10/4/04 and 9/7/05 and restated below.**

Altman teaches a drug delivery device for methods of injecting therapeutic agents into the myocardium through a distensible penetrating element with a chamber for holding the agent (se e.g. abstract). Specifically, the device is designed to penetrate the endocardium and inject drugs deep into the myocardium (see e.g. col 3, line 9-25). Agents are delivered in microformulations such as microspheres or nanoparticles or polymers (see e.g. col 12, line 29-30). The agents are delivered using a tubular "means for delivery", which is a means of delivery disclosed by the instant specification. The agents are in microspheres or nanoparticles, which are

locally delivered to the myocardium. The combination of the nanoparticles and drug delivery catheter would be said to place the agents in "a form for local delivery" as recited in claim 1. 4 and 32. Numerous agents are envisioned for delivery such as small molecules and macromolecules such as growth factors and polymers, which would fill the voids (see e.g. col 11 line 1 through 30 and figure 4a) as recited in claims 3, 6, and 7. The device comprises a penetrating end and is a hollow tube such as a needle (see e.g. col 4, line 11-12). Furthermore, an expansile cutter is included with the device. This expansile cutter is comprised of an expanding prong fixation that is sharpened to penetrate and spread the tissue (see e.g. col 9, line 22-44) as recited in claim 15, 19 and 25. The device comprises a needle and is thus comprised of metal as recited in claim 16. The drug delivery tube is comprised of a catheter and is thus flexible as recited in claim 17, 36 and 37 (see e.g. col 4, line 41-45) and is connected to reservoir (col 3, line 9-25) as recited in claim 18. Osmotic pumps or piston chambers drive drug delivery as recited in claims 21-23 (see e.g. col 6, line 40 through col 7, line 12) and is guided by a guiding catheter (see e.g. col 12, line 61-63) as recited in claim 23. The expansile cutters, create a void into which is deposited the agents for delivery (see e.g. col 10, line 48-54) as recited in claim 34.

Claims 1, 3, 4, 6, 7, 14-16, 18, 20-24, 32 and 34-37 are rejected under 35 U.S.C. 102(e) as being anticipated by Haim et al, (US 6,309,370 B1; see entire document). **This rejection is maintained from the office action mailed 10/4/04 and 9/7/05 and restated below.**

Haim et al teach an apparatus for intracardiac administration of growth factors into the myocardium (see e.g. abstract and col 3, line 24-42). Agents are delivered in microcapsules (see

e.g. col 7, line 6-16). The agents are delivered using a catheter or tubular "means for delivery", which is a means of delivery disclosed by the instant specification. Given the lack of disclosure as to the form the agents are in for "local delivery", the combination of the microcapsules and drug delivery catheter would be said to place the agents in "a form for local delivery" as recited in claim 1. As well, Haim et al teach that the drugs can be delivered using polymer slow release formulations (col 3, line 30-35) as recited in claims 4 and 32. Growth factor drugs such as FGF or VEGF are envisioned for delivery (see e.g. col 9 line 4-10) as recited in claims 3, 6 and 7. The device comprises a laser beam that conveys a wave-guide to create channels into which the drugs are deposited (see e.g. col 5, line 20-21 and col 6, line 41-44) as recited in claims 14 and 34. The drug delivery device comprises a hollow needle, which is inserted into the heart with a laser beam that conveys a wave-guide to create channels or voids (see e.g. col 5, line 20-21 and col 6, line 41-44) as recited in claim 15. The device comprises a needle and is thus comprised of metal as recited in claim 16 and tubular as recited in claim 36. The device is connected to reservoir (col 13, line 1-15) as recited in claim 18 and delivered by pumps and is guided by a guiding catheter (see e.g. col 7, line 25-31) as recited in claims 21-23. A series of sensors for guidance, a position sensor and a optical sensor and one for identification of sites, a physiological sensor, a pressure sensor, an ultrasound sensor (see e.g. col 3, line through col 6, line 28) as recited in claim 20, 24. The organ can be accessed percutaneously (see e.g. col 6, line 30-59) as recited in claim 35.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 13 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Altman (US 6,585,716 B2; see entire document) or Altman (US 6,102,887; see entire document) or Haim et al, (US 6,309,370 B1; see entire document) in view of Benjamin and McMillan (Circ Res, 1998, Vol 83, pages 117-132; see entire document). **This rejection is maintained from the office action mailed 10/4/04 and 9/7/05 and restated below.**

Applicants claim a method, devices and kits for treatment comprising locally penetrating and entering the body of an organ to gain access to an endomural zone. The device deposits drugs such as heat shock proteins (HSP) into the endomural zone.

The teachings of Altman, Altman and Haim et al are described above and are applied as before except; neither Altman, Altman and Haim et al teach use of heat shock proteins.

Benjamin and McMillan teach that HSP enhances the speed of recovery of the Ischemic Heart (see e.g. page 119, col 2).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the drugs and growth factors taught by Altman, Altman and Haim et al with the HSPs taught by Benjamin and McMillan because Altman, Altman and Haim et al et al teach that it is within the ordinary skill of the art to deliver drugs to the myocardium to treat cardiac vascular disease and because Benjamin and McMillan teach that it is within the ordinary

skill of the art to enhance recovery of an ischemic heart with administration of hsps. One would have been motivated to do so in order to receive the expected benefit of improved myocardial function, preserved metabolic functional recovery, reduction of infarct size (see e.g. page 119, col 2). Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brosamle et al (The Journal of Neurosciences, 2000, Vol 20:21, pages 8061-8068; see entire document) in view of Altman (US 6,585,716 B2; see entire document) or Altman (US 6,102,887; see entire document) or Haim et al, (US 6,309,370 B1; see entire document). **This rejection is maintained from the office action mailed 10/4/04 and 9/7/05 and restated below.**

Applicants claim a method, devices and kits for treatment comprising locally penetrating and entering the body of an organ to gain access to an endomural zone. Applicants recite a use of kits comprising devices and a void filling material for nerve regeneration.

Brosamle et al teach the use of a device in which recombinant humanized IN-1 Fad antibody is delivered through by a pump through a catheter to the intrathecal space of the spinal cord. Specifically, a small hole in the dura matter was made and a catheter connected to a small osmotic pump was inserted into the subdural space close to the lesion (see e.g. figure 4). Following administration of rIN-1 Fab induced regeneration of transected spinal cord axons was induced (see e.g. page 8065, col 1, paragraph 3).

Brosamle et al do not teach that the device has an end penetrating or cutting means with which the device is inserted into the endomural zone.

The teachings of Altman, Altman and Haim et al are described above and are applied as before.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the device and methods of treatment for nerve regeneration of Brosamle et al with the device of Altman, Altman and Haim et al because Brosamle et al teach that it is within the ordinary skill of the art to administer drugs through a catheter into the subdural space for infusion into a lesion and because Altman, Altman and Haim et al et al teach that it is within the ordinary skill of the art to use a drug delivery device that delivers drugs into the depths of the tissue. One would have been motivated to do so in order to receive the expected benefit of minimally invasive delivery of drugs in a local sustained manner for more effective drug effects (see e.g. US 6,309,370, col 2, line 50 through col 3, line 11). Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Response to Argument

Applicants traverse the claim rejections under 35 U.S.C. 102 and 103 on pages 12-16 of the amendment filed 9/25/06. Applicants argue 1) Altman '716 doesn't teach cutting or removal of tissue or a means for guidance 2) Altman '877 doesn't teach creating a void or a means for guidance 3) Haim doesn't disclose use of a carrier or methods of creating of a void 4) none of the combined references cures the deficiencies.

Applicants' arguments filed 9/25/06 have been fully considered but they are not persuasive. The instant specification teaches "Voids may be created by simple catheter, trochar or needle insertion." As well, the specification teaches that "(t)he void may be of identical size to the insertion device." (see page 11, line 22). Therefore, by insertion of a needle as taught by Altman '716, Altman '877 and Haim et al, there is inherent cutting and removal of tissue that was in the path of the needle, which is supported by the instant disclosure that teaches that the means for creating a void is met by use of a needle. Altman '877 also teaches use of an expansile cutter. This cutter is designed to distend and spread the tissue apart which may be for stabilization. However, this is a secondary function of the expansile cutter "It is also possible that the prongs be made of a softer more blunt structure that is not designed to penetrate the tissue... high durometer polymer material, such as polyurethane could be formed into structures that would stabilize the penetrating element" (col 9, line 44-50). However, this section specifically teaches "The prongs are designed to penetrate the body tissue and spread apart when the penetrating drug delivery element (the needles 865) advances axially out the distal end". Hence, the expansile cutter combined with the delivery needle creates a void in the target tissue which is the endocardium of the heart. As to means for guidance, Altman '716 and Altman '877 specifically teach use of a catheter guide in column 4, line 11 and col 12, line 64-65 respectively. As to use of a carrier, Haim et al teach "controlled release" of liquid and soluble compound such as by use of polymer based slow release methods (col 3, line 30-35). These carriers are used to encases drugs and only allow sustained slow release of the contents.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B. Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (7:00-4:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, PhD can be reached on (571)-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maria B Marvich, PhD
Examiner
Art Unit 1633